Complete Summary

GUIDELINE TITLE

Screening for colorectal cancer: U.S. Preventive Services Task Force recommendation statement.

BIBLIOGRAPHIC SOURCE(S)

U.S. Preventive Services Task Force. Screening for colorectal cancer: U.S. Preventive Services Task Force recommendation statement. Ann Intern Med 2008 Nov 4;149(9):627-37. PubMed

GUIDELINE STATUS

This is the current release of the guideline.

This release updates a previously published guideline: U.S. Preventive Services Task Force. Screening for colorectal cancer: recommendation and rationale. Ann Intern Med. 2002;137:129-31.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Colorectal cancer

GUIDELINE CATEGORY

Prevention
Screening

CLINICAL SPECIALTY

Family Practice
Gastroenterology
Geriatrics
Internal Medicine
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To summarize the U.S. Preventive Services Task Force (USPSTF) recommendations and supporting evidence on screening for colorectal cancer
- To update the 2002 USPSTF recommendations on screening for colorectal cancer

TARGET POPULATION

Adults 50 years of age or older

Note: These recommendations exclude persons with specific inherited syndromes (Lynch syndrome or familial adenomatous polyposis) and those with inflammatory bowel disease.

INTERVENTIONS AND PRACTICES CONSIDERED

Screening for colorectal cancer using flexible sigmoidoscopy (FS), colonoscopy, computed tomography (CT) colonography, and fecal screening tests

MAJOR OUTCOMES CONSIDERED

Key Question 1: What is the effectiveness of the following screening methods (alone or in combination) in reducing mortality from colorectal cancer: flexible sigmoidoscopy (FS), colonoscopy, computed tomography (CT) colonography (CTC), fecal screening tests (high-sensitivity guaiac fecal occult blood testing [HS-FOBT], fecal immunological test [FIT], or fecal DNA tests)?

Key Question 2a: What are the sensitivity and specificity of (1) colonoscopy, and (2) FS when used to screen for colorectal cancer (CRC) in the community practice setting?

Key Question 2b: What are the test performance characteristics of (1) CTC and (2) fecal screening tests for CRC screening as compared to an acceptable reference standard?

Key Question 3a: What are age-specific rates of harm from colonoscopy and FS in the community practice setting?

Key Questions 3b: What are the adverse effects of newer tests including CTC and/or fecal screening tests (HS-FOBT, FIT, and fecal DNA)?

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): A targeted, updated systematic evidence review was prepared by the Oregon Evidence-based Practice Center (EPC) for use by the U.S. Preventive Services Task Force (USPSTF) (see the "Availability of Companion Documents" field).

Searches and Selection Process

In brief, EPC staff searched PubMed, Database of Abstracts of Reviews of Effects (DARE), the Cochrane Database of Systematic Reviews (CDSR), Institute of Medicine (IOM), National Institute for Health and Clinical Excellence (NICE), and Health Technology Assessment (HTA) databases for recent systematic reviews (1999–2006) to support their review of all key questions. They found 11 existing systematic reviews for newer colorectal cancer screening tests (key question 2b). Using methods detailed in the Appendix in the Systematic Review (see the "Availability of Companion Documents" field), EPC staff selected 3 good-quality reviews of computed tomographic (CT) colonography or fecal DNA testing to locate relevant primary studies; these were supplemented with additional MEDLINE and Cochrane Library searches from January 2006 through January 2008 to locate additional studies published after the end date of the searches. Because there were no good-quality relevant systematic reviews for reports on fecal immunochemical tests (key questions 2b and 3b), EPC staff searched MEDLINE and the Cochrane Library (1990–2008) and from 2000 to 2008 to locate studies of the harms of screening tests (key questions 3a and 3b) since the 2002 report.

Abstracts and articles were dual-reviewed against inclusion criteria (Appendix in the Systematic Review [see the "Availability of Companion Documents" field]) and required agreement of 2 reviewers. Eligible studies reported on the sensitivity and specificity of colorectal cancer screening tests or on health outcomes. Studies that did not address average-risk populations for colorectal cancer screening were excluded, unless an average-risk subgroup was reported. Case–control studies of screening accuracy were excluded because these may overestimate sensitivity as a design-related source of bias, as recently demonstrated for fecal occult blood tests (FOBTs). To avoid biases related to reference standards, studies of test accuracy that incompletely applied a valid reference standard or used an

inadequate reference standard were excluded. For CT colonography, EPC staff considered only technologies that were compared with colonoscopy in average-risk populations, used a multidetector scanner, and reported per-patient sensitivity and specificity. In all, 3948 abstracts and 490 full-text articles were evaluated (Figure 2 in the Evidence Synthesis [see the "Availability of Companion Documents" field]).

NUMBER OF SOURCE DOCUMENTS

In all, 3948 abstracts and 490 full-text articles were evaluated.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Decision Analysis
Meta-Analysis
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): A targeted, updated systematic evidence review was prepared by the Oregon Evidence-based Practice Center (EPC) for use by the U.S. Preventive Services Task Force (USPSTF) (see the "Availability of Companion Documents" field). The USPSTF also commissioned a decision analytic modeling analysis using population modeling techniques to compare the expected health outcomes and resource requirements of available screening modalities when used in a programmatic way over time (see the "Availability of Companion Documents" field).

Quality Assessment and Data Abstraction

Two investigators critically appraised and quality-rated all eligible studies by using design-specific USPSTF criteria supplemented by other criteria (Appendix in the Systematic Review [see the "Availability of Companion Documents" field). Poor-quality studies were excluded. One investigator abstracted key elements of included studies into standardized evidence tables. A second reviewer verified these data. Disagreements about data abstraction or quality appraisal were resolved by consensus. Evidence tables and tables of excluded studies for each key question are available in the full Evidence Synthesis (see the "Availability of Companion Documents" field).

Data Synthesis and Analysis

Qualitative synthesis of the results is reported for most key questions because of study heterogeneity. The performance of screening tests is preferentially described per person (sensitivity and specificity), supplemented by per-polyp analyses (miss rates). Sensitivity for large adenomas from 2 similar studies of computed tomographic (CT) colonography screening was combined by using the inverse variance fixed-effects model because no heterogeneity was detected on the basis of the Cochran Q test and the I^2 statistic. Because of the stringency of the inclusion criteria for studies to estimate rates of endoscopy harms in the community practice setting (key question 3a), included studies were clinically homogeneous enough to pool. A random-effects logistic model was used to evaluate statistical heterogeneity, estimate pooled rates, and explore potential sources of variation for complications from study-level characteristics. Model details and SAS PROC NLMIXED code are provided in the Appendix of the Systematic Review (see the "Availability of Companion Documents" field). Total serious adverse events required hospital admission (for example, perforation, major bleeding, severe abdominal symptoms, and cardiovascular events) or resulted in death. Results of exploratory analyses for potential sources of variation for pooled estimates are discussed in the full report, along with pooled estimates for individual complications, such as perforations.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Balance Sheets
Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The U.S. Preventive Services Task Force (USPSTF) systematically reviews the evidence concerning both the benefits and harms of widespread implementation of a preventive service. It then assesses the certainty of the evidence and the magnitude of the benefits and harms. On the basis of this assessment, the USPSTF assigns a letter grade to each preventive service signifying its recommendation about provision of the service (see Table below). An important, but often challenging, step is determining the balance between benefits and harms to estimate "net benefit" (that is, benefits minus harms).

Table 1. U.S. Preventive Services Task Force Recommendation Grid*

Certainty of Net Benefit	Magnitude of Net Benefit			
	Substantial	Moderate	Small	Zero/Negative
High	A	B	C	D
Moderate	B	B	C	D
Low	Insufficient			

**A*, *B*, *C*, *D*, and *I (Insufficient)* represent the letter grades of recommendation or statement of insufficient evidence assigned by the U.S. Preventive Services Task Force after assessing certainty and magnitude of net benefit of the service (see the "Rating Scheme for the Strength of the Recommendations" field).

The overarching question that the Task Force seeks to answer for every preventive service is whether evidence suggests that provision of the service would improve health outcomes if implemented in a general primary care population. For screening topics, this standard could be met by a large randomized, controlled trial (RCT) in a representative asymptomatic population with follow-up of all members of both the group "invited for screening" and the group "not invited for screening."

Direct RCT evidence about screening is often unavailable, so the Task Force considers indirect evidence. To guide its selection of indirect evidence, the Task Force constructs a "chain of evidence" within an analytic framework. For each key question, the body of pertinent literature is critically appraised, focusing on the following 6 questions:

1. Do the studies have the appropriate research design to answer the key question(s)?
2. To what extent are the existing studies of high quality? (i.e., what is the internal validity?)
3. To what extent are the results of the studies generalizable to the general U.S. primary care population and situation? (i.e., what is the external validity?)
4. How many studies have been conducted that address the key question(s)? How large are the studies? (i.e., what is the precision of the evidence?)
5. How consistent are the results of the studies?
6. Are there additional factors that assist us in drawing conclusions (e.g., presence or absence of dose–response effects, fit within a biologic model)?

The next step in the Task Force process is to use the evidence from the key questions to assess whether there would be net benefit if the service were implemented. In 2001, the USPSTF published an article that documented its systematic processes of evidence evaluation and recommendation development. At that time, the Task Force's overall assessment of evidence was described as good, fair, or poor. The Task Force realized that this rating seemed to apply only to how well studies were conducted and did not fully capture all of the issues that go into an overall assessment of the evidence about net benefit. To avoid confusion, the USPSTF has changed its terminology. Whereas individual study quality will continue to be characterized as good, fair, or poor, the term *certainty* will now be used to describe the Task Force's assessment of the overall body of evidence about net benefit of a preventive service and the likelihood that the assessment is correct. Certainty will be determined by considering all 6 questions listed above; the judgment about certainty will be described as high, moderate, or low.

In making its assessment of certainty about net benefit, the evaluation of the evidence from each key question plays a primary role. It is important to note that the Task Force makes recommendations for real-world medical practice in the United States and must determine to what extent the evidence for each key question—even evidence from screening RCTs or treatment RCTs—can be applied to the general primary care population. Frequently, studies are conducted in highly selected populations under special conditions. The Task Force must consider differences between the general primary care population and the populations studied in RCTs and make judgments about the likelihood of observing the same effect in actual practice.

It is also important to note that 1 of the key questions in the analytic framework refers to the potential harms of the preventive service. The Task Force considers the evidence about the benefits and harms of preventive services separately and equally. Data about harms are often obtained from observational studies because harms observed in RCTs may not be representative of those found in usual practice and because some harms are not completely measured and reported in RCTs.

Putting the body of evidence for all key questions together as a chain, the Task Force assesses the certainty of net benefit of a preventive service by asking the 6 major questions listed above. The Task Force would rate a body of convincing evidence about the benefits of a service that, for example, derives from several RCTs of screening in which the estimate of benefits can be generalized to the general primary care population as "high" certainty (see the "Rating Scheme for the Strength of Recommendations" field). The Task Force would rate a body of evidence that was not clearly applicable to general practice or has other defects in quality, research design, or consistency of studies as "moderate" certainty. Certainty is "low" when, for example, there are gaps in the evidence linking parts of the analytic framework, when evidence to determine the harms of treatment is unavailable, or when evidence about the benefits of treatment is insufficient. Table 4 in the methodology document listed below (see "Availability of Companion Documents" field) summarizes the current terminology used by the Task Force to describe the critical assessment of evidence at all 3 levels: individual studies, key questions, and overall certainty of net benefit of the preventive service.

Sawaya GF, et al. Update on the methods of the U.S. Preventive Services Task Force: estimating certainty and magnitude of net benefit. Ann Intern Med. 2007;147:871-875 [5 references].

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

What the United States Preventive Services Task Force (USPSTF) Grades Mean and Suggestions for Practice

Grade	Grade Definitions	Suggestions for Practice
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer or provide this service.
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.	Offer or provide this service.
C	The USPSTF recommends against routinely providing the service. There may be considerations that support providing the service in an individual patient. There is moderate or high certainty that the net benefit is small.	Offer or provide this service only if there are other considerations in support of the offering/providing the service in an individual patient.
D	The USPSTF recommends against	Discourage the use of this service.

Grade	Grade Definitions	Suggestions for Practice
	the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	
I Statement	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality or conflicting, and the balance of benefits and harms cannot be determined.	Read "Clinical Considerations" section of USPSTF Recommendation Statement (see "Major Recommendations" field). If offered, patients should understand the uncertainty about the balance of benefits and harms.

USPSTF Levels of Certainty Regarding Net Benefit

Definition: The U.S. Preventive Services Task Force defines certainty as "likelihood that the USPSTF assessment of the net benefit of a preventive service is correct." The net benefit is defined as benefit minus harm of the preventive service as implemented in a general, primary care population. The USPSTF assigns a certainty level based on the nature of the overall evidence available to assess the net benefit of a preventive service.

Level of Certainty	Description
High	The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.
Moderate	The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by factors such as: • The number, size, or quality of individual studies • Inconsistency of findings across individual studies • Limited generalizability of findings to routine primary care practice • Lack of coherence in the chain of evidence As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.
Low	The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of: • The limited number or size of studies • Important flaws in study design or methods • Inconsistency of findings across individual studies • Gaps in the chain of evidence • Findings not generalizable to routine primary care practice

Level of Certainty	Description
	• A lack of information on important health outcomes More information may allow an estimation of effects on health outcomes.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Comparison with Guidelines from Other Groups
External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Peer Review. Before the U.S. Preventive Services Task Force (USPSTF) makes its final determinations about recommendations on a given preventive service, the Evidence-based Practice Center (EPC) and the Agency for Healthcare Research and Quality (AHRQ) send a draft systematic evidence review to 4 to 6 external experts and to federal agencies and professional and disease-based health organizations with interests in the topic. They ask the experts to examine the review critically for accuracy and completeness and to respond to a series of specific questions about the document. After assembling these external review comments and documenting the proposed response to key comments, the topic team presents this information to the Task Force in memo form. In this way, the Task Force can consider these external comments and a final version of the systematic review before it votes on its recommendations about the service. Draft recommendations are then circulated for comment from reviewers representing professional societies, voluntary organizations and Federal agencies. These comments are discussed before the whole U.S. Preventive Services Task Force before final recommendations are confirmed.

Recommendations of Others. Recommendations for screening for colorectal cancer from the following groups were discussed: the American Cancer Society, the U.S. Multi-Society Task Force on Colorectal Cancer, the American College of Radiology, the American College of Obstetricians and Gynecologists, the Canadian Task Force on Preventive Health Care, the American College of Physicians, the American Academy of Family Physicians, the American College of Preventive Medicine, and the Centers for Disease Control and Prevention.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The US Preventive Services Task Force (USPSTF) grades its recommendations (A, B, C, D, or I) and identifies the Levels of Certainty regarding Net Benefit (High,

Moderate, and Low). The definitions of these grades can be found at the end of the "Major Recommendations" field.

Summary of Recommendations and Evidence

The USPSTF recommends screening for colorectal cancer using fecal occult blood testing, sigmoidoscopy, or colonoscopy, in adults, beginning at age 50 years and continuing until age 75 years. The risks and benefits of these screening methods vary. (See Rationale section of the original guideline document.) **This is an A recommendation**.

The USPSTF recommends against routine screening for colorectal cancer in adults 76 to 85 years. There may be considerations that support colorectal cancer screening in an individual patient. **This is a C recommendation**.

The USPSTF recommends against screening for colorectal cancer in adults older than age 85 years. **This is a D recommendation**.

The USPSTF concludes that the evidence is insufficient to assess the benefits and harms of computed tomographic colonography and fecal DNA testing as screening modalities for colorectal cancer. **This is an I statement**.

Clinical Considerations

Patient Population under Consideration

These recommendations apply to adults 50 years of age and older, excluding those with specific inherited syndromes (Lynch syndrome or familial adenomatous polyposis) and those with inflammatory bowel disease. The recommendations do apply to those with first-degree relatives who have had colorectal adenomas or cancer, although for those with first-degree relatives who developed cancer at a younger age, or with multiple affected first-degree relatives, an earlier start to screening may be reasonable. Data suggest that colorectal cancer has a higher mortality rate in African Americans. The reasons for this differential are not well known, and the recommendations are intended to apply to all ethnic and racial groups.

When the screening test results in the diagnosis of clinically significant colorectal adenomas or cancer, the patient will be followed by a surveillance regimen and recommendations for screening are no longer applicable. The USPSTF did not address evidence for the effectiveness of any particular surveillance regimen after diagnosis and/or removal of adenomatous polyps.

Screening Tests

The relative sensitivity and specificity of the different colorectal screening tests with adequate data to assess cancer detection—colonoscopy, flexible sigmoidoscopy, and fecal tests—can be depicted as follows:

> Sensitivity: Hemoccult II < fecal immunochemical tests $\leq$ Hemoccult SENSA < flexible sigmoidoscopy < colonoscopy

Specificity: Hemoccult SENSA < fecal immunochemical tests ≈ Hemoccult II < flexible sigmoidoscopy = colonoscopy

For the operator-dependent tests—flexible sigmoidoscopy, computed tomographic (CT) colonography, and colonoscopy—better operator training and more experience have a high likelihood of improving sensitivity. Approaches related to certification, such as quality standards and possibly minimum volume requirements, could be used to achieve the goal of improving operator performance and therefore test sensitivity. Assurance of performance of high-quality endoscopy should be part of all screening programs.

Since several screening strategies have similar efficacy, efforts to reduce colon cancer deaths should focus on implementation of strategies that maximize the number of individuals who get screening of some type. The different options for colorectal cancer screening tests are variably acceptable to patients; eliciting patient preferences is one step in improving adherence. Ideally, shared decision making between clinicians and patients would incorporate information on local test availability and quality as well as patient preference.

Screening Intervals and Starting and Stopping Ages

Screening for colorectal cancer reduces mortality through detection and treatment of early stage cancers and detection and removal of adenomatous polyps. The degree to which each of these mechanisms contributes to a reduction in mortality is unknown, though it is likely that the largest reduction in colorectal cancer mortality during the 10 years after initial screening comes from the detection and removal of early-stage cancers. Colonoscopy is a necessary step in any screening program that reduces mortality from colorectal cancer. This reduction in mortality does come at the expense of significant morbidity associated with colonoscopy. Evidence does not currently allow a differential estimate of colonoscopy-related morbidity for different age groups or for exams done with or without biopsy.

In this context, the best measure for the morbidity that results from any screening program for colorectal cancer is the number of colonoscopies required to achieve a reduction in mortality. Although improvements in mortality will generally be associated with increasing morbidity that results from the screening and surveillance program, the goal of a screening program should be to maximize the number of life-years gained while minimizing the harms.

In a report prepared for the USPSTF by 2 groups in the Cancer Intervention and Surveillance Modeling Network (CISNET), investigators conducted microsimulation analyses that applied programs of screening to standard populations of adults in the United States. These analyses permitted a comparison of expected outcomes among testing strategies involving the fecal tests, flexible sigmoidoscopy, or colonoscopy (as noted below). In the models, the predicted total number of colonoscopies included those resulting from surveillance after detection of colorectal neoplasia. The models assumed lifetime monitoring by colonoscopy every 3 to 5 years depending on the number and size of the adenomas detected. It is not the intent of the USPSTF to endorse this particular approach to surveillance, but standardizing the approach to surveillance is necessary to compare screening strategies in the models.

For all screening modalities, starting screening at age 50 resulted in a balance between life-years gained and colonoscopy risks that was more favorable than commencing screening earlier. Despite the increasing incidence of colorectal adenomas with age, for individuals previously screened the gain in life-years associated with extending screening from age 75 to 85 was small in comparison to the risks of screening people in this decade. For adults who have not previously been screened, decisions about first-time screening in this age group should be made in the context of the individual's health status and competing risks, given that the benefit of screening is not seen in trials until at least 7 years later. For individuals older than age 85, competing causes of mortality preclude a mortality benefit that outweighs the harms.

Screening programs incorporating fecal occult blood testing, sigmoidoscopy, or colonoscopy will all be effective in reducing mortality. Modeling evidence suggests that population screening programs between the ages of 50 and 75 using any of the following 3 regimens will be approximately equally effective in life-years gained, assuming 100% adherence to the same regimen for that period: 1) annual high-sensitivity fecal occult blood testing, 2) sigmoidoscopy every 5 years combined with high-sensitivity fecal occult blood testing every 3 years, and 3) screening colonoscopy at intervals of 10 years.

The strategies differ in the total number of colonoscopies that would be required to gain similar numbers of life-years. The first strategy, use of annual high-sensitivity fecal occult blood testing (sensitivity for cancer $\geq$70%) that has a false-positive rate less than 10% (that is, specificity >90%) is estimated to require the fewest colonoscopies while achieving a gain in life-years similar to that seen with screening colonoscopy every 10 years. Currently available tests that meet both specifications include SENSA guaiac testing (Beckman Coulter, Fullerton, California) and fecal immunochemical tests with characteristics similar to those of the Magstream quantitative test (Fujirebio Inc., Tokyo, Japan).

Although use of an annual fecal occult blood screening test with a lower sensitivity has been demonstrated to reduce colorectal cancer mortality in randomized, controlled trials, modeling suggests that the number of life-years gained will be greater with the strategies using higher-sensitivity tests.

For all screening modalities, the effectiveness decreases substantially as adherence to the regimen declines. At the individual level, adherence to a screening regimen will be more important in life-years gained than will the particular regimen selected. Current data are insufficient to predict adherence to any specific screening regimen at the population level.

Considerations for Practice When Evidence Is Insufficient

CT Colonography

Potential preventable burden. A screening program that incorporates the option of CT colonography could help reduce colorectal cancer mortality in the population if patients who would otherwise refuse screening found it an acceptable alternative.

Potential harms. The potential harms from evaluation of incidental findings found with CT colonography may be large. The lifetime cumulative radiation risk from

use of CT colonography to screen for colorectal cancer should be considered, as well as the growing cumulative radiation exposure from the use of other kinds of diagnostic and screening that involve radiation exposure.

Current practice. Computed tomographic colonography performed by trained and experienced radiographers may not be currently available in many parts of the United States.

Costs. Patient time and burden to participate in colorectal cancer screening using test strategies that require bowel preparation are substantial. A CT colonography screening strategy that did not involve bowel preparation would decrease the burden of adherence. The cost of CT colonography is high.

Fecal DNA

Potential preventable burden. Fecal DNA has potential as a highly specific test, and it could reduce harms associated with follow-up of false-positive test results.

Current practice. Fecal DNA tests are evolving, and no test is widely used.

Costs. Fecal DNA is likely to have a high monetary cost per test.

Other Approaches to Prevention

Dietary approaches, such as avoidance of red meat and alcohol or consumption of diets very high in fiber, have been suggested to protect against the risk for colorectal adenomas, but these claims are based on associations present in observational studies that have thus far not been substantiated in trials. Certain nonsteroidal anti-inflammatory drugs (NSAIDs) are associated with regression and decreased incidence of colonic adenomas, but the harms of daily NSAID use in asymptomatic persons led the USPSTF to recommend against this use in persons not at increased risk.

Definitions:

What the United States Preventive Services Task Force (USPSTF) Grades Mean and Suggestions for Practice

Grade	Grade Definitions	Suggestions for Practice
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer or provide this service.
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.	Offer or provide this service.
C	The USPSTF recommends against routinely providing the service. There may be considerations that	Offer or provide this service only if there are other considerations in support of the offering/providing the

Grade	Grade Definitions	Suggestions for Practice
	support providing the service in an individual patient. There is moderate or high certainty that the net benefit is small.	service in an individual patient.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I Statement	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality or conflicting, and the balance of benefits and harms cannot be determined.	Read "Clinical Considerations" section of USPSTF Recommendation Statement (see "Major Recommendations" field). If offered, patients should understand the uncertainty about the balance of benefits and harms.

USPSTF Levels of Certainty Regarding Net Benefit

Definition: The U.S. Preventive Services Task Force defines certainty as "likelihood that the USPSTF assessment of the net benefit of a preventive service is correct." The net benefit is defined as benefit minus harm of the preventive service as implemented in a general, primary care population. The USPSTF assigns a certainty level based on the nature of the overall evidence available to assess the net benefit of a preventive service.

Level of Certainty	Description
High	The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.
Moderate	The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by factors such as: • The number, size, or quality of individual studies • Inconsistency of findings across individual studies • Limited generalizability of findings to routine primary care practice • Lack of coherence in the chain of evidence As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.
Low	The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of:

Level of Certainty	Description
	• The limited number or size of studies • Important flaws in study design or methods • Inconsistency of findings across individual studies • Gaps in the chain of evidence • Findings not generalizable to routine primary care practice • A lack of information on important health outcomes More information may allow an estimation of effects on health outcomes.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Benefits of Detection and Early Intervention

- There is convincing evidence that screening with any of the 3 recommended tests reduces colorectal cancer mortality in adults age 50 to 75 years. Follow-up of positive screening test results requires colonoscopy regardless of the screening test used. Because of the harms of colonoscopy described below, the chief benefit of less invasive screening tests is that they may reduce the number of colonoscopies required and their attendant risks.
- There is adequate evidence that the benefits of detection and early intervention decline after age 75. There is a substantial lead time between the detection and treatment of colorectal neoplasia and a mortality benefit, and competing causes of mortality make it progressively less likely that this benefit will be realized with advancing age.

POTENTIAL HARMS

Harms of Detection and Early Intervention

The primary established harms of colorectal cancer screening are due to the use of invasive procedures initially or in the evaluation sequence. Harms may arise from the preparation the patient undergoes to have the procedure, the sedation used during the procedure, and the procedure itself.

Colonoscopy

Evidence is adequate to estimate the harms of colonoscopy. In the United States, perforation of the colon occurs in an estimated 3.8 per 10,000 procedures. Serious complications—defined as deaths attributable to colonoscopy or adverse events requiring hospital admission, including perforation, major bleeding, diverticulitis, severe abdominal pain, and cardiovascular events—are significantly more common, occurring in an estimated 25 per 10,000 procedures.

Flexible Sigmoidoscopy

Evidence is adequate that serious complications occur in approximately 3.4 per 10,000 procedures.

Fecal Tests

Evidence about the harms of fecal tests is lacking (inadequate), but the U.S. Preventive Services Task Force (USPSTF) assesses them to be no greater than small.

Computed Tomographic (CT) Colonography

- Computed tomographic colonography images more than the colon. At least 10% of people having their first CT colonography are found to have extracolonic abnormalities that require further testing. Evidence is inadequate to assess the clinical consequences of identifying these abnormalities, but there is potential for both benefit and harm. Potential harms arise from additional diagnostic testing and procedures for lesions found incidentally, which may have no clinical significance. This additional testing also has the potential to burden the patient and adversely impact the health system.
- The risks for perforation associated with CT colonography in research settings are estimated to be 0 to 6 per 10,000 CT colonography studies. However, these estimates may be higher than what can be expected in screened populations because the studies included symptomatic populations.
- Radiation exposure resulting from CT colonography is reported to be 10 mSv per examination. The harms of radiation at this dose are not certain, but the linear-no-threshold model predicts that 1 additional individual per 1000 would develop cancer in his or her lifetime at this level of exposure. The lifetime cumulative radiation risk from the use of CT colonography to screen for colorectal cancer should be considered in the context of the growing cumulative radiation exposure from the use of other diagnostic and screening tests that involve radiation exposure. On the other hand, improvements in CT colonography technology and practice are lowering this radiation dose.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- The U.S. Preventive Services Task Force (USPSTF) makes recommendations about preventive care services for patients without recognized signs or symptoms of the target condition.

- Recommendations are based on a systematic review of the evidence of the benefits and harms and an assessment of the net benefit of the service.
- The USPSTF recognizes that clinical or policy decisions involve more considerations than this body of evidence alone. Clinicians and policy-makers should understand the evidence but individualize decision making to the specific patient or situation.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

The experiences of the first and second U.S. Preventive Services Task Force (USPSTF), as well as that of other evidence-based guideline efforts, have highlighted the importance of identifying effective ways to implement clinical recommendations. Practice guidelines are relatively weak tools for changing clinical practice when used in isolation. To effect change, guidelines must be coupled with strategies to improve their acceptance and feasibility. Such strategies include enlisting the support of local opinion leaders, using reminder systems for clinicians and patients, adopting standing orders, and audit and feedback of information to clinicians about their compliance with recommended practice.

In the case of preventive services guidelines, implementation needs to go beyond traditional dissemination and promotion efforts to recognize the added patient and clinician barriers that affect preventive care. These include clinicians' ambivalence about whether preventive medicine is part of their job, the psychological and practical challenges that patients face in changing behaviors, lack of access to health care or of insurance coverage for preventive services for some patients, competing pressures within the context of shorter office visits, and the lack of organized systems in most practices to ensure the delivery of recommended preventive care.

Dissemination strategies have changed dramatically in this age of electronic information. While recognizing the continuing value of journals and other print formats for dissemination, the Agency for Healthcare Research and Quality will make all U.S. Preventive Services Task Force (USPSTF) products available through its Web site. The combination of electronic access and extensive material in the public domain should make it easier for a broad audience of users to access U.S. Preventive Services Task Force materials and adapt them for their local needs. Online access to U.S. Preventive Services Task Force products also opens up new possibilities for the appearance of the annual, pocket-size *Guide to Clinical Preventive Services*.

To be successful, approaches for implementing prevention have to be tailored to the local level and deal with the specific barriers at a given site, typically requiring the redesign of systems of care. Such a systems approach to prevention has had notable success in established staff-model health maintenance organizations, by addressing organization of care, emphasizing a philosophy of prevention, and altering the training and incentives for clinicians. Staff-model plans also benefit from integrated information systems that can track the use of needed services and generate automatic reminders aimed at patients and clinicians, some of the

most consistently successful interventions. Information systems remain a major challenge for individual clinicians' offices, however, as well as for looser affiliations of practices in network-model managed care and independent practice associations, where data on patient visits, referrals, and test results are not always centralized.

IMPLEMENTATION TOOLS

Foreign Language Translations
Patient Resources
Personal Digital Assistant (PDA) Downloads
Pocket Guide/Reference Cards
Resources
Staff Training/Competency Material

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

U.S. Preventive Services Task Force. Screening for colorectal cancer: U.S. Preventive Services Task Force recommendation statement. Ann Intern Med 2008 Nov 4;149(9):627-37. PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1996 (revised 2008 Oct)

GUIDELINE DEVELOPER(S)

United States Preventive Services Task Force - Independent Expert Panel

GUIDELINE DEVELOPER COMMENT

The U.S. Preventive Services Task Force (USPSTF) is a Federally-appointed panel of independent experts. Conclusions of the U.S. Preventive Services Task Force do not necessarily reflect policy of the U.S. Department of Health and Human Services (DHHS) or its agencies.

SOURCE(S) OF FUNDING

United States Government

GUIDELINE COMMITTEE

U.S. Preventive Services Task Force (USPSTF)

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

*Task Force Members**: Ned Calonge, MD, MPH, *Chair* (Colorado Department of Public Health and Environment, Denver, Colorado); Diana B. Petitti, MD, MPH , *Vice-Chair* (Keck School of Medicine, University of Southern California, Sierra Madre, California); Thomas G. DeWitt, MD (Children's Hospital Medical Center, Cincinnati, Ohio); Allen J. Dietrich, MD (Dartmouth Medical School, Hanover, New Hampshire); Kimberly D. Gregory, MD, MPH (Cedars-Sinai Medical Center, Los Angeles, California); Russell Harris, MD, MPH (University of North Carolina School of Medicine, Chapel Hill, North Carolina); George Isham, MD, MS (HealthPartners Inc., Minneapolis, Minnesota); Michael L. LeFevre, MD, MSPH (University of Missouri School of Medicine, Columbia, Missouri); Roseanne M. Leipzig, MD, PhD (Mount Sinai School of Medicine, New York, New York): Carol Loveland-Cherry, PhD, RN (University of Michigan School of Nursing, Ann Arbor, Michigan); Lucy N. Marion, PhD, RN (School of Nursing, Medical College of Georgia, Augusta, Georgia); Bernadette Melnyk, PhD, RN (Arizona State University College of Nursing & Healthcare Innovation, Phoenix, Arizona); Virginia A. Moyer, MD, MPH (University of Texas Health Science Center, Houston, Texas); Judith K. Ockene, PhD (University of Massachusetts Medical School, Worcester, Massachusetts); George F. Sawaya, MD (University of California, San Francisco, California); and Barbara P. Yawn, MD, MSPH, MSc (Olmsted Medical Center, Rochester, Minnesota).

**Members of the Task Force at the time this recommendation was finalized. For a list of current Task Force members, go to* www.ahrq.gov/clinic/uspstfab.htm.

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

The U.S. Preventive Services Task Force has an explicit policy concerning conflict of interest. All members disclose at each meeting if they have a significant financial, professional/business, or intellectual conflict for each topic being discussed. Task Force members with conflicts may be recused from discussing or voting on recommendations about the topic in question.

GUIDELINE STATUS

This is the current release of the guideline.

This release updates a previously published guideline: U.S. Preventive Services Task Force. Screening for colorectal cancer: recommendation and rationale. Ann Intern Med. 2002;137:129-31.

GUIDELINE AVAILABILITY

Electronic copies: Available from the U.S. Preventive Services Task Force (USPSTF) Web site and the Annals of Internal Medicine Web site.

Print copies: Available from the Agency for Healthcare Research and Quality (AHRQ) Publications Clearinghouse. For more information, go to http://www.ahrq.gov/news/pubsix.htm or call 1-800-358-9295 (U.S. only).

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

Evidence Reviews:

- Whitlock EP, Lin J, Liles E, Beil T, Fu R, O'Connor E, Thompson RN, Cardenas T. Screening for colorectal cancer: an updated systematic review. Evidence Synthesis No. 65, Part 1. AHRQ Publication No. 08-05124-EF-1. Rockville, Maryland, Agency for Healthcare Research and Quality, October 2008. Electronic copies: Available from the U.S. Preventive Services Task Force (USPSTF) Web site.
- Zauber AG, Lansdorp-Vogelaar I, Knudson AB, Wilschut J, van Ballegooijen M, Kuntz KM. Evaluating test strategies for colorectal cancer screening: age to begin, age to stop, and timing of screening intervals. Decision analysis of colorectal cancer screening for the U.S. Preventive Services Task Force from the Cancer Intervention and Surveillance Modelling Network (CISNET). Evidence Synthesis No. 65, Part 2. AHRQ Publication No. 08-05124-EF-2. Rockville, Maryland, Agency for Healthcare Research and Quality, October 2008. Electronic copies: Available from the U.S. Preventive Services Task Force (USPSTF) Web site.
- Whitlock EP, Lin JS, Liles E, Beil TL, Fu R. Screening for colorectal cancer: a targeted, updated systematic review for the U.S. Preventive Services Task Force. Ann Intern Med. 2008;149:638-658. Electronic copies: Available from the U.S. Preventive Services Task Force (USPSTF) Web site and the Annals of Internal Medicine Web site.
- Zauber AG, Lansdorp-Vogelaar I, Knudson AB, Wilschut J, van Ballegooijen M, Kuntz KM. Evaluating test strategies for colorectal cancer screening: a decision analysis for the U.S. Preventive Services Task Force. Ann Intern Med. 2008;149:659-669. Electronic copies: Available from the U.S. Preventive Services Task Force (USPSTF) Web site and the Annals of Internal Medicine Web site.

Electronic copies: Available from the U.S. Preventive Services Task Force (USPSTF) Web site.

The following are also available:

- Screening for colorectal cancer: clinical summary of U.S. Preventive Services Task Force recommendations. 2008. Electronic copies: Available in Portable Document Format (PDF) from the U.S. Preventive Services Task Force (USPSTF) Web site.
- A continuing medical education (CME) activity is available from the Annals of Internal Medicine Web site.
- An audio summary podcast is available from the Annals of Internal Medicine Web site.

Background Articles:

- Barton M et al. How to read the new recommendation statement: methods update from the U.S. Preventive Services Task Force. Ann Intern Med. 2007;147:123-127.
- Guirguis-Blake J et al. Current processes of the U.S. Preventive Services Task Force: refining evidence-based recommendation development. Ann Intern Med. 2007;147:117-122. [2 references]
- Sawaya GF et al., Update on the methods of the U.S. Preventive Services Task Force: estimating certainty and magnitude of net benefit. Ann Intern Med. 2007;147:871-875. [5 references].

Electronic copies: Available from U.S. Preventive Services Task Force (USPSTF) Web site.

The following is also available:

- The guide to clinical preventive services, 2008. Recommendations of the U.S. Preventive Services Task Force. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ), 2008. 243 p AHRQ Publication No. 08-05122. Electronic copies available from the AHRQ Web site. See the related QualityTool summary on the Health Care Innovations Exchange Web site.

Print copies: Available from the Agency for Healthcare Research and Quality Publications Clearinghouse. For more information, go to http://www.ahrq.gov/news/pubsix.htm or call 1-800-358-9295 (U.S. only).

The Electronic Preventive Services Selector (ePSS), available as a PDA application and a web-based tool, is a quick hands-on tool designed to help primary care clinicians identify the screening, counseling, and preventive medication services that are appropriate for their patients. It is based on current recommendations of the USPSTF and can be searched by specific patient characteristics such as age, sex, and selected behavioral risk factors.

PATIENT RESOURCES

The following are available:

- Screening for colorectal cancer: U.S. Preventive Services Task Force recommendation. Summaries for patients. 2008. Available from the Annals of Internal Medicine Web site.
- Men: Stay Healthy at Any Age – Checklist for Your Next Checkup. Rockville (MD): Agency for Healthcare Research and Quality. AHRQ Pub. No. 07-IP006-A. February 2007. Electronic copies: Available in English and Spanish from the USPSTF Web site. See the related QualityTool summary on the Health Care Innovations Exchange Web site.
- Women: Stay Healthy at Any Age – Checklist for Your Next Checkup. Rockville (MD): Agency for Healthcare Research and Quality. AHRQ Pub. No. 07-IP005-A. February 2007. Electronic copies: Available in English and Spanish from the USPSTF Web site. See the related QualityTool summary on the Health Care Innovations Exchange Web site.

Print copies: Available from the Agency for Healthcare Research and Quality (AHRQ) Publications Clearinghouse. For more information, go to http://www.ahrq.gov/news/pubsix.htm or call 1-800-358-9295 (U.S. only).

Myhealthfinder is a new tool that provides personalized recommendations for clinical preventive services specific to the user's age, gender, and pregnancy status. It features evidence-based recommendations from the USPSTF and is available at www.healthfinder.gov.

NGC STATUS

This summary was completed by ECRI on July 8, 2002. The information was verified by the guideline developer on July 11, 2002. This summary was updated by ECRI Institute on November 12, 2008. The updated information was verified by the guideline developer on February 2, 2009.

COPYRIGHT STATEMENT

DISCLAIMER

NGC DISCLAIMER

The National Guideline Clearinghouse™ (NGC) does not develop, produce, approve, or endorse the guidelines represented on this site.

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC Inclusion Criteria which may be found at http://www.guideline.gov/about/inclusion.aspx .

NGC, AHRQ, and its contractor ECRI Institute make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI Institute, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.

Date Modified: 2/23/2009